How to Complete Form ADP 8045 Physician Request for a Temporary Exception to Regulations

Program information

Complete the program information on the top of the form. Please ensure the accuracy of the information such as the NTP license number issued by the Department.

Nature of request

Mark only one box for the type of regulatory exception being requested. A brief summary of each is as follows:

1. <u>State Admission Exception</u>: Title 9, Section 10270(d)(1), requires a program that does not have a state admission (two-plus-two) exception to obtain prior approval from the Department before admitting a patient who does not have the required two-year documented history of addiction. Enter the discharge dates of the **two most recent treatment episodes.**

When granting an admission exception, the Department <u>cannot</u> be less stringent than federal regulations, Section 291.505(d)(1), which states a program physician must determine that the person is currently physiologically dependent upon a narcotic drug for at least one-year prior to admission. Therefore, the program physician must determine that the patient has at least a one-year history of addiction prior to admission to comply with federal law.

2. <u>Above 100 mg Take-Home Exception</u>: Title 9, Section 10370(c), states when a patient's medication dosage level exceeds 100 mg (101 mg and above), <u>prior approval</u> from the Department <u>and</u> the federal Food and Drug Administration is required for the patient to receive **more than one take-home per week.**

This approval does not need to be renewed as dose levels increase or decrease above the 100 mg level, or when take-home medication schedules change.

- 3. <u>Over Seven (7) Days Exceptional Circumstance</u>: Title 9, Section 10385(a)(2), limits the exception for vacation or other necessary travel to seven days unless approval is obtained from ADP to exceed the regulatory authority.
 - If the request is less than 14 days, FDA approval is not required. The physician may grant up to a seven day supply without State approval.
- 4. Over Fourteen (14) Days Exceptional Circumstance: Title 9, Section 10385(a)(2), and CFR 291.505(d)(6)(vi)(B) limits the exception for vacation or other necessary travel to 14 day supply unless approval is obtained from ADP and FDA to exceed the regulatory authority.

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- 5. Over Fourteen (14) Days Physical Disability or Chronic, Acute, or Terminal Illness: Title 9, Section 10385(a)(1), and CFR 291.505(d)(6)(vi)(A) limits the exception for medical situations to 14 days. The physician may grant up to a two-week supply without State/FDA approval. If over 14 days, State/FDA must approve.
- 6. <u>Urinalysis Testing</u>: Title 9, Section 10310(e) requires monthly testing of each patient in maintenance treatment and CFR 291.505(d)(2)(i) requires at least eight random tests be performed in the first year of maintenance treatment; at least quarterly for each subsequent year, except that a random test is performed monthly on each patient who receives a 6-day supply of take-home medication. A physician may request an exception for patients who have a medical condition that inhibits the patient's ability to provide a urine sample.
- 7. <u>Other</u>: The program physician has the option to request any exception to regulations (i.e., a request to admit a pregnant minor to maintenance treatment).

Patient's record number

The record number is the number assigned by the program to the patient's medical record when the patient is admitted for treatment.

Patient's admission date

The date the patient was admitted to the current program submitting the request.

Patient's dosing information

The need for ADP approval for take-home dosages over 100 mg may result either from a need to increase the dosage amount or reduce the patient's attendance at the clinic. Therefore, provide the requested dosing information based on what the patient's dosing arrangements will be if the approval is granted (i.e., dosage level, type of medication, and take-home step level).

Dates of take-homes

The date the first and last dose of the medication will be ingested away from the program.

Treatment failures

The discharge dates of any two treatment failures. This may include documentation of two failed detoxification or other treatment episodes.

Physician

Please describe all circumstances surrounding the patient's situation which justifies the

justification	request for the exception.
Physician signature and date	The authorized program physician's signature, printed name, and date he or she requested the exception to regulations.
